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SCHWEGMAN, LUNDBERG & WOESSNER, P.A.
P.O. BOX 2938
MINNEAPOLIS, MN 55402

EXAMINER	
HINES, JANA A	

ART UNIT	PAPER NUMBER
1645	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/661,094	DODGSON, KIRSTY JANE	
	Examiner	Art Unit	
	Ja-Na Hines	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 May 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-43* is/are pending in the application.

4a) Of the above claim(s) *2-7,10-14,20-22,24 and 26-43* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,8,9,15-19,23,25 and 43-49* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Amendment Entry

1. The amendment filed May 4, 2007 has been entered. Claims 1, 8-9, 15, 19 and 23 have been amended. Claims 2-7,10-14, 20-22, 24 and 26-43 have been withdrawn from consideration. Claims 44-49 have been newly added. Claims 1, 8-9, 15-19, 23,25 and 43-49 are under consideration in this office action.

Withdrawal of Rejections

2. The following rejections have been withdrawn in view of applicants' amendments and arguments:

a) The rejection of claims 1, 15-18, 23 and 25 under 35 U.S.C. 102(b) as being anticipated by Petrich et al., (Mol. and Cellular Probes, 1999, Vol. 13:275-281);

b) The rejection of claims 1, 8-9, 15-19, 23 and 25 under 35 U.S.C. 102(b) as being anticipated by Modrusan (US Patent 6,274,316);

c) The objection to claims 15, 19 and 23;

Response to Arguments

3. Applicant's arguments with respect to claims 1, 8-9, 15-19, 23,25 and 43-49 have been considered but are moot in view of the new ground(s) of rejection.

New Grounds of Rejection Necessitated by Amendments

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1, 8-9, 15-19, 23, 25 and 43-49 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

Claim 1 is drawn to a method to detect vanA in a sample, comprising:

a) contacting a sample suspected of comprising amplified vanA nucleic acid with at least one vanA-specific oligonucleotide probe under conditions effective to form a hybrid between the vanA-specific oligonucleotide probe and vanA nucleic acid in the sample, wherein the vanA-specific oligonucleotide probe has about 15 to 40 nucleotides with at least 80% nucleic acid sequence identity to SEQ ID NO:3 or the complement of SEQ ID NO:3, wherein the amplified vanA nucleic acid is obtained with two oligonucleotide primers having about 15 to 40 nucleotides, wherein a first oligonucleotide primer has at least 80% nucleic acid sequence identity to SEQ ID NO:2, and a second oligonucleotide primer has at least 80% nucleic acid sequence identity to SEQ ID NO:4, wherein the probe is capable of hybridizing to SEQ ID NO:3 or its complement, wherein the first

primer is capable of hybridizing to the complement of SEQ ID NO:2, and wherein the second primer is capable of hybridizing to the complement of SEQ ID NO:4; and b) detecting or determining the presence or amount of hybrid formation, wherein hybrid formation is indicative of vanA nucleic acid in the sample.

The specification teaches the structure of only a single representative species of SEQ ID NO:2, 3 and 4. Moreover, the specification fails to describe any other representative species by any identifying characteristics or properties other than the functionality of being capable of hybridizing to SEQ ID NO:2, 3 or 4. Given this lack of description of representative species encompassed by the genus of the claim, the specification fails to sufficiently describe the claimed invention in such full, clear, concise, and exact terms that a skilled artisan would recognize that applicants were in possession of the claimed invention.

No information, beyond the characterization of a probes having SEQ ID NO:3 and primers having SEQ ID NO:3 and 4 have been provided, which would indicate that applicants had possession of the claimed genus of any probes and primers that are about 15 to 40 nucleotides with at least 80% sequence identity to SEQ ID NO:2, 3 or 4. The specification does not contain any disclosure of the structure of variants falling within the scope of the claimed genus. The genus of the probes and primers claimed is a large variable genus including mutants and variants, which can have wide variety of structures. The specification discloses the structure of only a single representative species of the claimed genus i.e. SEQ ID NO: 2, 3 and 4 which is insufficient to put one of skill in the art in possession of the attributes and features of all species within the

claimed genus. Therefore, one skilled in the art cannot reasonably conclude that applicant had possession of the claimed invention at the time the instant application was filed.

With respect to claims 1, 8,9 and 46-49, there is no description of polypeptides having at least 80%, 85%, 90% or 95% sequence identity to. Sequences having at least 80%, 85%, 90%, 95% or 97% sequence identity to SEQ ID NO:2, 3 or 4. Oligonucleotides having about 15 to 40 nucleotides with at least 80% sequence identity to SEQ ID NO:2, 3 or 4 fail to meet the written description provision of 35 UCS 112, first paragraph. *Vas-Cath Inc. V. Mahurkar*, 19 USPQ2d 1111, make clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed." (See page 1117). The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116). The specification only discloses SEQ ID NO:2,3 and 4 there is no disclosure of oligonucleotide sequences with at least 80%, 85%, 90% or 95% sequence identity to SEQ ID NO:2, 3 and 4. Thus, the structure of these oligonucleotides are not defined. Even though the claims recite SEQ ID NO:2, 3 and 4 the skilled artisan cannot envision the detailed structure of the sequences having at least 80%, 85%, 90% or 95% sequence identity since the specification has failed to define what nucleotides are essential for their performance in the method of detection. For example, Petrich et al., (Mol. and Cellular Probes, 1999, Vol. 13:275-281) do not teach oligonucleotide sequences having about

15 to 40 nucleotides with at least 80% sequence identity to SEQ ID NO:2, 3 or 4 and capable of hybridizing to their respective sequences. Therefore, there is no description of any oligonucleotides having the instantly recited characteristics.

Therefore, conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method for determining sequence identity. Adequate written description requires more than a mere statement that it is part of the invention and a reference to a potential method of expression. The nucleic acid itself is required. See *Fiers v. Revel*, 25 USPQ 2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. V. Chugai Pharmaceutical Co. Lts.*, 18 USPQ2d 1016.

Furthermore, the specification does not place any structure, chemical functional limitations on the polynucleotide probe per se. It is noted that the nucleic acid molecule is capable of hybridizing to SEQ ID NO:2, 3 or 4. The recitation of primers being capable of hybridization does not convey a common structure or function. The scope of the claims includes numerous structural variants and the genus is highly variant because a significant number of structural differences between the genus members are permitted. The specification fails to provide guidance on the structure of the primers. Structural features that could distinguish molecules in the genus from others in the class are missing from the disclosure and the claims. No common structural attributes identify the members of the genus. The general knowledge and level of skill in the art do not supplement the omitted description, because specific, not general guidance is needed. The specification and claims lack sufficient written description of the generically claimed hybridizing primers which is defined by its function, i.e., to have the capability of

hybridizing. While the description of the ability of the claimed primers to hybridize, may describe the primer's function, it does not describe the primers themselves. The hybridization distinctions are purely functional distinctions which are insufficient.

The MPEP further states that if a biomolecule is described only by a functional characteristic, without any disclosed correlation between function and structure of the sequence, it is "not sufficient characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence." MPEP 2163. The MPEP does state that for generic claim the genus can be adequately described if the disclosure presents a sufficient number of representative species that encompass the genus. MPEP 2163. If the genus has a substantial variance, the disclosure must describe a sufficient variety of species to reflect the variation within that genus. See MPEP 2163. Although the MPEP does not define what constitute a sufficient number of representative, the Courts have indicated what do not constitute a representative number species to adequately describe a broad generic. In Gostelli, the Court determined that the disclosure of two chemical compounds within a subgenus did not describe that subgenus. In re Gostelli, 872 F.2d at 1012, 10 USPQ2d at 1618. Since the disclosure fails to describe the common attributes or structural characteristics that identify the members of the genus, and because the genus of nucleic acid molecules of is highly variable, the function of hybridization alone is insufficient to describe the genus of nucleic acid molecules.

An adequate description requires more than a mere statement that it is part of the invention. The nucleic acid itself is required. See *Fiers v. Revel*, 25 USPQ 2d 1601

at 1606 (CAFC 1993) and *Amgen Inc. V. Chugai Pharmaceutical Co. Lts.*, 18 USPQ2d 1016. Encoding distinguishes the claimed nucleotide sequences from unclaimed sequences only by what they do, which is a purely functional distinction. Even where there is an actual reduction to practice, which may demonstrate possession of an embodiment of an invention, it does not necessarily describe what the claimed invention is. The instant claims describe a nucleic acid molecule described by its function i.e., hybridization, however this description does not describe the claimed nucleic acid molecules themselves. See also, *In The Reagents of the University of California v. Eli Lilly* (43 USPQ2d 1398-1412), where the court held that a generic statement that defines a genus of nucleic acids by only their functional activity does not provide an adequate description of the genus. The court indicated that while Applicants are not required to disclose every species encompassed by a genus, the description of a genus is achieved by the recitation of a representative number of DNA molecules, usually defined by a nucleotide sequence, falling within the scope of the claimed genus. At section B(1), the court states that "An adequate written description of a DNA...'requires a precise definition, such as by structure, formula, chemical name, or physical properties', not a mere wish or plan for obtaining the claimed chemical invention". Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 USC 112 is severable from its enablement provision (see page 115).

In view of these considerations, a person skilled in the art would not have viewed the teachings of the specification sufficient to show that applicants were in possession of the claimed probes and primers. Therefore the full breadth of the claims fails to meet the written description provision of 35 USC 112, first paragraph.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 1, 8-9, 15-19, 23, 25 and 43-49 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Neither the specification nor originally presented claims provides support for a method to detect vanA in a sample, comprising: a) contacting a sample suspected of comprising amplified vanA nucleic acid with at least one vanA-specific oligonucleotide probe under conditions effective to form a hybrid between the vanA-specific oligonucleotide probe and vanA nucleic acid in the sample, wherein the vanA-specific oligonucleotide probe has about 15 to 40 nucleotides with at least 80% nucleic acid sequence identity to SEQ ID NO:3 or the complement of SEQ ID NO:3, wherein the amplified vanA nucleic acid is obtained with two oligonucleotide primers having about 15 to 40 nucleotides, wherein a first oligonucleotide primer has at least 80% nucleic acid sequence identity to SEQ ID NO:2, and a second oligonucleotide primer has at least 80% nucleic acid sequence identity to SEQ ID NO:4, wherein the probe is capable of hybridizing to SEQ ID NO:3 or its complement, wherein the first primer is capable of

hybridizing to the complement of SEQ ID NO:2, and wherein the second primer is capable of hybridizing to the complement of SEQ ID NO:4; and b) detecting or determining the presence or amount of hybrid formation, wherein hybrid formation is indicative of vanA nucleic acid in the sample.

Applicant did not point to support in the specification for at least one vanA-specific oligonucleotide wherein the vanA-specific oligonucleotide probe has about 15 to 40 nucleotides with at least 80% nucleic acid sequence identity to SEQ ID NO:3 or the complement of SEQ ID NO:3 and is capable of hybridizing to SEQ ID NO:3;

a first oligonucleotide primer that has at least 80% nucleic acid sequence identity to SEQ ID NO:2, wherein the first primer is capable of hybridizing to the complement of SEQ ID NO:2, and a second oligonucleotide primer has at least 80% nucleic acid sequence identity to SEQ ID NO:4 and wherein the second primer is capable of hybridizing to the complement of SEQ ID NO:4. Moreover, applicants failed to specifically point to the identity or provide structural characteristics of the instantly claimed *vanA* specific oligonucleotide probe and primers. Thus, there appears to be no teaching of the *vanA* specific oligonucleotide probe that has about 15 to 40 nucleotides with at least 80% nucleic acid sequence identity to SEQ ID NO:3 or the complement of SEQ ID NO:3 and is capable of hybridizing to SEQ ID NO:3; a first oligonucleotide primer that has at least 80% nucleic acid sequence identity to SEQ ID NO:2, wherein the first primer is capable of hybridizing to the complement of SEQ ID NO:2, and a second oligonucleotide primer has at least 80% nucleic acid sequence identity to SEQ ID NO:4 and wherein the second primer is capable of hybridizing to the complement of

SEQ ID NO:4. The specification beginning at page s 13, 19, and 20 states oligonucleotides probes of different lengths and base composition may be used for detecting the *vanA* gene or the *vanB* gene, preferred oligonucleotides have lengths from 15 up to 40 nucleotides and are sufficiently homologous to the target nucleic acid to permit amplification of a *vanA* or *vanB* template and/or hybridization to such a template under high stringency conditions. However the specification fails to discloses probes and primers probe has about 15 to 40 nucleotides with at least 80% nucleic acid sequence identity to SEQ ID NO:3 or the complement of SEQ ID NO:3 and is capable of hybridizing to SEQ ID NO:3.Thus it appears that the entire specification appears to fail to recite support for the newly *vanA* specific oligonucleotide probe and oligonucleotide primers. Therefore, applicants must specifically point to page and line number support for the identity of the probe and primers. Accordingly, the claims incorporate new matter and are rejected.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 1, 8-9, 15-19, 23,25 and 43-49 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a) Claim 1 is unclear. A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered

indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, the claim is drawn to a *vanA-specific* oligonucleotide probe that has about 15 to 40 nucleotides with at least 80% nucleic acid sequence identity to SEQ ID NO:3 or the complement of SEQ ID NO:3; two oligonucleotide primers having about 15 to 40 nucleotides, wherein a first oligonucleotide primer has at least 80% nucleic acid sequence identity to SEQ ID NO:2; and a second oligonucleotide primer has at least 80% nucleic acid sequence identity SEQ ID NO:4. SEQ ID NO:2 has 18 amino acids, SEQ ID NO:3 has 27 amino acids and SEQ ID NO:4 has 20 amino acids. The “about language does not clarify the claim. It is unclear how applicants are defining the probes and primers. Claim 1 recites the broad limitation of having about 15 to 40 nucleotides, and the claim also recites SEQ ID NO:2, 3 and 4 which have 18, 27 and 20 nucleotides respectively, which is the narrower statement of the range/limitation. Thus the metes and bounds of the claim

cannot be ascertained by one of ordinary skill in the art and clarification is required to overcome the rejection.

b) The phrase "capable of hybridizing" in claim 1 is a relative phrase which renders the claim indefinite. The phrase is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The term selective is a term of degree and based upon parameters that are not defined in the specification or the claims. The specification at pages 21-22 teaches specific conditions such as having a PCR reaction mixtures containing 50mM KCl, 10mM Tris-HCl pH 8.3, 2.5 mM MgC12, 0.4/zm of each of the two primers, 200 uM of each of the four dNTPs and 1.25 Units of Taq DNA polymerase (Perkin Elmer). PCR reactions are then subjected to thermal cycling (3 minutes at 95°C followed by 30 cycles of 1 second at 95°C and 1 second at 55°C) using a Perkin Elmer 480 ™ thermal cycle and subsequently analyzed by standard ethidium bromide-stained agarose gel electrophoresis. As such, the term selectivity is dependant upon specific conditions that are not recited in the claims and specification fails to define the metes and bounds of the phrase. Therefore one skilled in the would not be readily apprised as to the metes and bounds of the hybridizing nucleic acids. Therefore, clarification is required to overcome the rejection.

Conclusion

7. No claims allowed.

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ja-Na Hines whose telephone number is 571-272-0859. The examiner can normally be reached on Monday-Thursday and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Jeffery Siew, can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ja-Na Hines
August 28, 2007

MARK NAVARRO
PRIMARY EXAMINER